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| 10/009,259   | 12/10/2001  | Jean-Pierre Grasa    | GR1520-BE9512                | 8595             |
| 466  | 7590        | 05/19/2004           | EXAMINER                     |                  |
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|  |             |                      | ART UNIT                     | PAPER NUMBER     |

1753

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/009,259

Applicant(s)

GRASA, JEAN-PIERRE

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12102001.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 1 and 12 are objected to because of the following informalities:
  - a) Claim 1: Applicant is requested to check the reference numbers for accuracy and consistency. For example “(26)” refers to a sensing electrode in line 10, but a retaining member in lines 16 and 14. Element “(70)” is referred to as a retaining member in the claim; however, in the specification “(9)” appears to be the retaining member (first full paragraph on page 14) and in Figure 11 “70” is used to label a “part” (last paragraph on page 21); and
  - b) Claim 12, line 7: -- and -- should be inserted before “capable.”
2. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

3. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 1, line 5: "termed reactive composition" should be deleted, or "termed reactive composition" should be substituted for "biochemical composition," or "termed" should be replaced with -- comprising a --;

b) Claim 1, line 6: "termed contact face" should be deleted, or "termed contact face" should be substituted for "free outer face," or "termed" should be replaced with -- comprising a --;

c) Claim 1, line 14; what does "it" refer to?

d) Claim 1, lines 14-16: what is facing the contact face?

e) Claim 5 appears to be inconstant with claim 1. Claim 1 require the retaining member to be at a distance from and facing the second electrode, yet claim 5 requires the retaining member to be formed of the second electrode;

f) Claim 5: does "is formed" mean -- contain --?

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- g) Claim 5: is a drop of liquid solution actually present in the claimed biosensor?
- h) Claim 6: does "an electrode" and the "two electrodes" refer to the first electrode and the second electrode of claim 1?
- i) Claim 8 recites the limitation "the assembly" in line 2. There is insufficient antecedent basis for this limitation in the claim;
- j) Claim 8, line 4: "termed receiving face" should be deleted and -- receiving -- should be inserted between "has" and "a" in line 3;
- k) Claim 8 recites the limitation "the horizontal" in line 6. There is insufficient antecedent basis for this limitation in the claim;
- l) Claim 8: is the range greater than 0° and less than 90° being claimed or just 40°?
- m) Claim 8 requires the receiving face to be a face of the contact face. How can a face have a face?
- n) Claim 9 requires the receiving face to be a face of the retaining member, but claims 1 and 10 require the receiving face to be a face of the reagent chamber;

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- o) Claim 12, line 6: "the" should be deleted;
- p) Claim 12, line 10; what does "it" refer to?
- q) Claim 12, line 3: how is the liquid reactive composition related to the reactive composition of claim 1?
- q) Claim 12, line 15: what is with an external electrical circuit?
- r) Claim 12, line 16: what is of the first electrode?
- s) Claim 12, lines 16-17: what is of a chip?
- t) Claim 12, line 19: "a chip" should be -- said chip --
- u) Claim 13 recites the limitation "the said inclined receiving face (25) of the semi-permeable membrane (9) of a chip (6)" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim;
- v) Claim 13 recites the limitation "the inclined receiving face" in line 6. There is insufficient antecedent basis for this limitation in the claim;

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w) Claim 13: if the face of the free end and the receiving face are substantially parallel to one another, what are they inclined with respect to?

x) Claim 14 recites the limitation "the receiving face" in line 3. There is insufficient antecedent basis for this limitation in claim 4;

y) Claim 14 recites the limitation "the mount" in line 4. There is insufficient antecedent basis for this limitation in the claim;

z) Claim 14 recites the limitation "the chip" in line 8. There is insufficient antecedent basis for this limitation in claim 4;

aa) Claim 14 recites the limitation "the gap" in line 13. There is insufficient antecedent basis for this limitation in the claim;

ab) Claim 15 recites the limitation "the said receiving face (25) of the semi-permeable membrane (9) of a chip (6) " in line 14. There is insufficient antecedent basis for this limitation in the claim;

ac) Claim 12 requires the chip, while claim 15 does not appear to require the chip. So, in claim 15, line 2, for example, "a chip" should be -- said chip --;

ad) Claim 16, line 1; what does "it" refer to?

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ae) Claim 17 recites the limitation "the receiving face" in line 4. There is insufficient antecedent basis for this limitation in the claim;

af) Claim 18, line 2; what does "it" refer to?

ag) Claim 19, line 2: "termed reactive composition" should be deleted, or "termed reactive composition" should be substituted for "biochemical composition," or "termed" should be replaced with -- comprising a --;

ah) Claim 19, line 12: "an electrode, termed" should be replaced with -- a --; and

ai) Claim 21, line 3: the comma (",") should be deleted.

4. Note that dependent claims will have the deficiencies of base and intervening claims.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.



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6. Claims 1-7, 19, and 26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the JPO computer English language translation of Tadahisa (JP 08-285814 A), hereafter "Tadahisa."

Addressing claim 1, Tadahisa teaches an electrochemical biosensor for measurement of the concentration of a compound in a liquid solution (abstract), comprising

a reagent chamber (10) adapted to enclose a quantity of biochemical composition comprising reactive composition (immobilized enzyme, see the abstract) and having a free face comprising a contact face (15) capable of being placed in contact with the liquid solution which is thus in contact with the reactive composition (Figure 1),

a first electrode (16) and a second electrode (15) which are adapted to be electrically connected to the liquid solution and to enable electrical measurement between them (Figure 1),

wherein it comprises, facing the contact face, a retaining member (12), the shape of this retaining member and the distance between the contact face and the retaining member being adapted so that a drop of liquid solution placed between the contact face and this retaining member is retained and maintained between them by capillary action (Figure 1 and paragraph [0016] of the "Detailed Description").

Addressing claim 2, the first electrode (16) is electrically connected to the reagent chamber (10), opposite the contact face (15), and the second electrode (14) is adapted to

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be electrically connected with the drop (18) of liquid solution on the side of the contact face (see Figure 1).

Addressing claim 3, as seen in Figure 1 the second electrode is adapted to be directly in contact with the drop of liquid solution.

Addressing claim 4, for the claimed electrically conductive intermediate element note in Figure 1 the lead or wire (19) connected to the second electrode.

Addressing claim 5, as seen in Figure 1 the retaining member is in contact with the drop of liquid solution.

Addressing claim 6, as seen in Figure 1 the retaining member is a specific member distinct from an electrode and the two electrodes are electrically connected to the reagent chamber.

Addressing claim 7, as seen in Figure 1 the retaining member has a face facing the contact face.

Addressing claim 19, Tadahisa teaches an electrochemical biosensor chip for measurement of the concentration of a compound in a liquid solution, wherein it comprises

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a reagent chamber (10) enclosing a quantity of liquid biochemical composition comprising reactive composition (enzyme immobilized in membrane 15) and having a semi-permeable membrane (15) having a free outer face (the bottom ace) capable of receiving a drop of liquid solution separated from the reactive composition by the semi-permeable membrane,

a first electrode (14) placed in electrical contact with eth reactive composition contained in the reagent chamber, and means for electrical connection (19) of this first electrode with an electrical circuit outside the chip.

Addressing claim 26, the chip in Tadahisa is a rectangular disc.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 11, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO computer English language translation of Tadahisa (JP 08-285814 A), hereafter "Tadahisa."

Tadahisa teaches an electrochemical biosensor for measurement of the concentration of a compound in a liquid solution (abstract), comprising

a reagent chamber (10) adapted to enclose a quantity of biochemical composition comprising reactive composition (immobilized enzyme, see the abstract) and having a free face comprising a contact face (15) capable of being placed in contact with the liquid solution which is thus in contact with the reactive composition (Figure 1),

a first electrode (16) and a second electrode (15) which are adapted to be electrically connected to the liquid solution and to enable electrical measurement between them (Figure 1),

wherein it comprises, facing the contact face, a retaining member (12), the shape of this retaining member and the distance between the contact face and the retaining member being adapted so that a drop of liquid solution placed between the contact face and this retaining member is retained and maintained between them by capillary action (Figure 1 and paragraph [0016] of the "Detailed Description").

Tadahisa does not mention the distance between the retaining member and the

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contact face, in particular whether the distance or less than 8 mm however, Tadahisa does teach that the distance is quite small, as a minute amount of sample drawn between electrodes by capillarity ("Effect of the Invention"). If the distance is not in fact less than 8 mm, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have the distance to be less than 8mm so that a smaller sample could be measured; in other words, it would have been obvious to scale the distance and other biosensor dimensions to the expected sample volume.

Addressing claims 27 and 28, Tadahisa teaches an electrochemical biosensor chip for measurement of the concentration of a compound in a liquid solution, wherein it comprises

a reagent chamber (10) enclosing a quantity of liquid biochemical composition comprising reactive composition (enzyme immobilized in membrane 15) and having a semi-permeable membrane (15) having a free outer face (the bottom ace) capable of receiving a drop of liquid solution separated from the reactive composition by the semi-permeable membrane, a first electrode (14) placed in electrical contact with eth reactive composition contained in the reagent chamber, and means for electrical connection (19) of this first electrode with an electrical circuit outside the chip.

Tadahisa does not mention specific dimensions of the biosensor, in particular the thickness of the biosensor and any dimension of the electrodes; however, Tadahisa does teach that the distance is quite small, as a minute amount of sample drawn between electrodes by capillarity ("Effect of the Invention"). If the dimensions are not in fact as

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claimed, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have scale the biosensor dimensions to the expected sample volume.

10. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO computer English language translation of Tadahisa (JP 08-285814 A), hereafter "Tadahisa" in view of Shieh (US 6,054,039), hereafter "Shieh," or Diebold et al. (US 5,437,999), hereafter "Diebold."

Addressing claim 24, Tadahisa teaches an electrochemical biosensor chip for measurement of the concentration of a compound in a liquid solution, wherein it comprises

a reagent chamber (10) enclosing a quantity of liquid biochemical composition comprising reactive composition (enzyme immobilized in membrane 15) and having a semi-permeable membrane (15) having a free outer face (the bottom ace) capable of receiving a drop of liquid solution separated from the reactive composition by the semi-permeable membrane,

a first electrode (14) placed in electrical contact with eth reactive composition contained in the reagent chamber, and means for electrical connection (19) of this first electrode with an electrical circuit outside the chip.

Tadahisa does not mention an extension to the first electrodes emerging outside the chip in order to form means for electrical connection with an external electrical circuit.

Shieh and Diebold teaches biosensors in which the electrodes each have an extension emerging outside the biosensor in order to form means for electrical connection with an external electrical circuit (Figure 1B in Shieh and Figure 5 in Diebold). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide an extension as taught by Shieh or Diebold in the invention of Tadahisa because then the biosensor can be easily plugged into a meter or measuring means, instead having to attach wires for the connection.

11. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO computer English language translation of Tadahisa (JP 08-285814 A), hereafter "Tadahisa" in view of Ikeda et al. (US 6,416,641 B1), hereafter "Ikeda."

Addressing claim 29, Tadahisa teaches an electrochemical biosensor chip for measurement of the concentration of a compound in a liquid solution, wherein it comprises

a reagent chamber (10) enclosing a quantity of liquid biochemical composition comprising reactive composition (enzyme immobilized in membrane 15) and having a semi-permeable membrane (15) having a free outer face (the bottom ace) capable of receiving a drop of liquid solution separated from the reactive composition by the semi-permeable membrane, a first electrode (14) placed in electrical contact with eth reactive composition contained in the reagent chamber, and means for electrical connection (19) of this first electrode with an electrical circuit outside the chip.

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Tadahisa does not mention having the reaction composition as an enzymatic aqueous solution immobilizing glucose oxidase by well-known approaches is disclosed ([0014] in 'Example').

Ikeda teaches a biosensor comprising an aqueous glucose oxidase reaction layer (col. 6, ll. 21-35). Barring evidence to the contrary, such as unexpected results, the choice of immobilization method for an enzymatic reaction composition in an electrochemical biosensor from known immobilization methods is just a matter of convenience or optimizing the biosensor.

***Allowable Subject Matter***

12. Claims 8-10, 12, 13, 14/4, 14/13, 15-18, 20-23, and 25 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 8: the nonobvious improvement is that the combination of limitations requires the receiving face to have an angle of inclination with respect to horizontal which is greater than  $0^{\circ}$  and less than  $90^{\circ}$ . As seen in Figure 1 of



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Tadahisa the receiving face is parallel to the electrodes and the longitudinal axis of the sample chamber;

b) Claims 9 and 10 depend from allowable claim 8;

c) Claim 12: the nonobvious improvement is that the combination of limitations requires a chip comprising the first electrode and a mount comprising means for receiving the chip. In Tadahisa the electrodes are integral with their supports (mounts) as the electrodes as formed by vapor deposition or sputtering, for example ([0014] in "Example");

d) Claim 13: the nonobvious improvement is that the combination of limitations requires the free end of the second electrode to face the receiving face of the semi-permeable membrane of a chip. In Tadahisa the membrane is on the second electrode (Figure 1). Also, the faces of the electrodes and their respective supporting substrates are parallel to one another;

e) Claim 14/13 depends from allowable claim 13;

f) Claim 14/4: the nonobvious improvement is that the combination of limitations requires a liquid-solution supply shaft emerging immediately upstream of and facing the free face of the second electrode so that the liquid solution is supplied and deposited on this free face to flow downwards along the second electrode

until it comes into the gap separating the second electrode and the inclined receiving face. In Tadahisa a drop of sample is deposited at the edge of the biosensor by means external to the biosensor and then the sample directly flows between the two electrodes because of capillarity.

g) Claims 15, 17, and 18 depend from allowable claim 12;

h) Claim 16 depend from allowable claim 15;

i) Claim 20: the nonobvious improvement is that the combination of limitations requires the first electrode to have an end emerging in the reagent chamber opposite a portion of the semi-permeable membrane forming the receiving face. As seen In Figure 1 of Tadahisa the first electrode is adjacent and in contact with the membrane. The second electrode is opposite a portion of the membrane. Also, neither electrode has an end emerging in the reagent chamber;

j) Claim 21: the nonobvious improvement is that the combination of limitations in requires the first electrode to form a bottom of the reagent chamber which is closed, opposite this bottom by the semi-permeable membrane. In Tadahisa the first electrode forms a top of the reagent chamber and the reagent chamber is closed, opposite this top by the second electrode;

k) Claims 22 and 23 depend from allowable claim 21; and


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l) Claim 25: the nonobvious improvement is that the combination of limitations in requires the first electrode to traverse the thickness of the body. In Tadahisa the electrodes only lie along the surface of the support bodies.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Alex Noguerola  
Primary Examiner  
AU 1753  
May 14, 2004